QA Operations Specialist

Job ID
REQ-10054371

6月 16, 2025

USA

摘要

Our QA Operations Specialist manages Quality aspects and projects within area of responsibility as well as ensuring and supporting overall GxP conformity and Compliance with the Novartis Quality Management Systems for the Millburn manufacturing site.

Location: Millburn, NJ #LI-Onsite

Shift: Monday-Friday day shift

About the Role

Key Responsibilities:

- Provide QA support of production, engineering, and supply chain operations through review/approval of test records for batch release, SOPs, C of As (as applicable), CAPAs,

Deviations, change controls, and shop floor oversight. Provides the production, engineering, and supply chain teams with QA/Compliance guidance and decisions.
- Review and approve Standard Operating Procedures (SOPs), Quality Risk Assessments (QRAs), Quality Plans related to manufacturing operations, as needed. Contribute to generation of Annual Product Reviews for production, engineering and supply chain.
- Support continuous quality improvement program for manufacturing operations and partner with the production, engineering, and supply chain teams to implement/optimizes to improve efficiency (right the first time) and monitor/escalate as needed.
- Supports all regulatory inspections related to preparedness initiatives and executions of the inspections.
- Provide cGMP and associated OJT training to any other quality members and other operational areas as needed.
- Perform or support any other tasks necessary to maintain the product quality and site cGMP compliance, as needed.
- Supports QA Operations programs especially related to batch release activities and shop floor programs which includes Visual Monitoring on Surprise (ViMOS), GEMBA walkthrough program, equipment/area/utility out of service program, QA area release of classified and unclassified areas, QA media fill oversight programs, event triage and support of routine operations.
- Assist in triaging when an event or issue arises during manufacturing operations Follow the scheduling of tasks set forth by the QA operations Lead or Head for shop floor coverage including ViMOS, GEMBA
- Review/approve investigations of excursions in production, engineering, and supply chain operations.
- Support resolution of major and critical quality events, monitor that recurrent events are properly escalated and resolved. Ensure root cause is determined, evaluate impact on product quality, disposition, and corrective actions.
- Perform final review of production data test data/reports to ensure conformance to the established specifications and standard operating procedures. Act as Responsible Person for the final disposition of products.
- Follow the scheduling of tasks set forth by the QA operations Lead or Head for batch record issuance and record review and release activities

Essential Requirements

- Education: Bachelors' Degree, preferably in Life Sciences, Chemistry or related relevant degree.
- 2+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations
- 1+ years of experience in a quality assurance role
- Collaborating across boundaries
- Functional Breadth
- QA and/or QC experience in pharmaceutical industry with environmental monitoring & cleanliness zones
- Experience with investigation and root cause including OOX investigation expertise strongly preferred.

The salary for this position is expected to range between $$81,200 and $150,800 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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+1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
New Jersey

站点
Millburn

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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